

CLAIMS:

1. A composition for nasal delivery comprising zolpidem or a pharmaceutically acceptable salt thereof.

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2. A composition according to claim 1 in the form of a solution or a powder.

3. A composition according to claim 2 in the form of an aqueous solution.

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4. A composition according to any one of the preceding claims comprising a salt of zolpidem selected from the hydrochloride, mesilate, citrate, nitrate, lactate, maleate, tartrate, phosphate, succinate, fumarate and gluconate salts.

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5. A composition according to claim 4, wherein the salt is the tartrate salt.

6. A composition according to any one of the preceding claims, which is in the form of a solution and comprising from 0.8 to 97 mg/ml of zolpidem (expressed as the free base).

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7. A composition according to claim 6, comprising from 24 to 80 mg/ml of zolpidem (expressed as the free base).

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8. A composition according to claim 6, comprising from 2.4 to 16 mg/ml of zolpidem (expressed as the free base).

9. A composition according to any one of the preceding claims in the form of a solution and comprising a solubility enhancing agent.

10. A composition according to claim 9, wherein the solubility enhancing agent is a cyclodextrin.
- 5 11. A composition according to claim 10, wherein the cyclodextrin is sulfobutylether- β -cyclodextrin (SBE-CD).
12. A composition according to claim 11, comprising 50 to 700 mg/ml SBE-CD.
- 10 13. A composition according to any one of the preceding claims having a pH of from 3.0 to 8.0.
14. A composition according to any one of the preceding claims additionally
15 comprising chitosan, a salt, a derivative thereof or a salt of a derivative thereof.
15. A composition according to claim 14, comprising from 0.5 to 50 mg/ml of chitosan, a salt, a derivative thereof or a salt of a derivative thereof.
- 20 16. A composition according to claim 1, which is an aqueous solution and comprises from 30 to 60 mg/ml of zolpidem tartrate, 100 to 300 mg/ml SBE-CD and 2 to 10 mg/ml of chitosan glutamate.
- 25 17. A composition according to claim 1, which is an aqueous solution and comprises from 3 to 20 mg/ml of zolpidem tartrate and 2 to 10 mg/ml of chitosan glutamate.

18. A composition according to any one of claims 1, 2 and 4 to 15, in the form of a non-aqueous solution.
19. A composition according to claim 18, comprising at least one of ethanol, propylene glycol, polyethylene glycol, glycofurol, benzyl benzoate and a polyoxyethylene castor oil derivative.
20. A composition according to any one of claims 1, 2, 4 and 5 in the form of a powder.
21. A composition according to claim 20, wherein the powder contains granules or microspheres.
22. A composition according to claim 20 or 21, comprising 20 to 70 % by weight of zolpidem (expressed as free base).
23. A composition according to any one of claims 20 to 22, further comprising a means for improving the rate of dissolution of zolpidem in the nasal cavity.
24. A composition according to claim 23, wherein the means is a cyclodextrin.
25. A composition according to claim 24, wherein the ratio by weight of zolpidem or a pharmaceutically acceptable thereof to cyclodextrin is from 1:0.25 to 1:10.
26. A composition according to claim 24 or 25, wherein the cyclodextrin is sulfobutylether- β -cyclodextrin (SBE-CD).

27. A composition according to any one of claims 20 to 26, further comprising chitosan, a salt, a derivative thereof or a salt of a derivative thereof.

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28. A composition according to claim 27, comprising from 5 to 50 % by weight of chitosan, a salt, a derivative thereof or a salt of a derivative thereof.

10 29. The use of zolpidem or a pharmaceutically acceptable salt thereof in the manufacture of a medicament for nasal administration to a patient in need thereof.

15 30. Use according to claim 29 in the manufacture of a medicament for the treatment or prevention of insomnia or for the treatment of a neurological disorder or for the treatment of Parkinson's disease.

31. Use according to claim 30, wherein the neurological disorder is one arising from brain trauma, stroke or spinocerebellar ataxia.

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32. A method of administering zolpidem or a pharmaceutically acceptable salt thereof to a patient in need thereof, which method comprise the intranasal administration of a composition as defined in any one of claims 1 to 28.

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33. A method of treating or preventing insomnia, which method comprises the intranasal administration of a composition as defined in any one of claims 1 to 28.

34. A method of treating a neurological disorder or Parkinson's disease, which method comprises the intranasal administration of a composition as defined in any one of claims 1 to 28.

5 35. A method according to claim 34, wherein the neurological disorder is one arising from brain trauma, stroke or spinocerebellar ataxia.

36. A nasal drug delivery device or a dose cartridge for use in a nasal drug delivery device comprising a composition as defined in any one of
10 claims 1 to 28.